

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	:	
	:	Group Art Unit: 2151
Vladislav Olchanski et al.	:	
	:	Examiner: Karen C. Tang
Appln. No.: 09/996,475	:	
	:	Confirmation No.: 2706
Filed: November 20, 2001	:	
	:	Customer No.: 21967
For: PERFORMANCE OUTCOMES	:	
BENCHMARKING	:	

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

This Reply Brief is submitted in reply to the Examiner's Answer, dated July 31, 2009, which responds to the Appellants' Appeal Brief, filed April 24, 2009. Appellants respectfully request that the Board of Patent Appeals and Interferences reconsider and reverse the rejections of record.

I. STATUS OF CLAIMS

Claims 1-21 and 23-30 are pending in the above-identified patent application. Claims 1-21 and 23-30 were finally rejected in the Office Action dated November 12, 2008. The final rejection of claims 1-21 and 23-30 is hereby appealed.

Claim 22 stands cancelled without prejudice.

Claims 1-21 and 23-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,675,640 to Gatts ("Gatts") in view of U.S. Patent No. 6,650,932 to Menzie et al. ("Menzie") and further in view of U.S. Patent No. 5,835,384 to Lin ("Lin").

II. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are to be reviewed on appeal.

Claims 1-21 and 23-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,675,640 to Gatts ("Gatts") in view of U.S. Patent No. 6,650,932 to Menzie et al. ("Menzie") and further in view of U.S. Patent No. 5,835,384 to Lin ("Lin").

III. ARGUMENTS

Appellants respectfully offer the following in reply to the new arguments, or arguments presented in a different manner for the first time, in the Examiner's Answer to the Appellants' Brief.

(i) The Examiner now asserts that the declaration and evidences (Exhibits A-G) under 37 C.F.R. 1.131 filed on May 25, 2007, and November 9, 2005, are insufficient to establish diligence from a data of conception to a constructive reduction to practice as well as actual reduction to practice. Appellants respectfully disagree. Appellants respectfully submit that the invention disclosed and claimed in the present application was conceived prior to May 15, 2000. Appellants also respectfully submit that they were duly diligent in preparing and filing the present application from the date of conception of the invention disclosed and claimed in the present application to the filing date of the present application (i.e., November 20, 2001). Also, Appellants respectfully submit that the declarations submitted on November 9, 2005, and May 27, 2007, provide a showing of conception prior to the Menzie reference date, as well as due diligence from prior to the Menzie reference date to both actual and constructive reduction to practice. Moreover,

upon completion of the active development of an initial version of the system embodying the claimed invention as described in the invention disclosure, Appellants filed U.S. Provisional Patent Application No. 60/252,129 on November 21, 2000. The present application claims priority to U.S. Provisional Patent Application No. 60/252,129.

(ii) The Examiner now asserts that cited art of record, (i.e., Gatts, Menzie, and Lin) did not teach away from one another and it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the cited art of record. Appellants respectfully disagree. In particular, the Examiner acknowledges, and Appellants agree, that Gatts fails to disclose, or even suggest, that "the second outcomes data sets are collected from the plurality of individuals," as recited in claim 1. However, the Examiner relies on Menzie to remedy such deficiency of Gatts. Furthermore, the Examiner relies on Lin to provide the motivation to combine Gatts and Menzie (e.g., to improve Gatt's system by efficiently collecting data from geographically dispersed devices and processing it in an efficient manner). Appellants respectfully submit that collecting medical data from geographically dispersed devices has no relationship with the

deficiency of Gatts (e.g., "the second outcomes data sets are collected from the plurality of individuals," as recited in claim 1). Thus, Appellants respectfully submit that collecting data from geographically dispersed devices and processing it in an efficient manner would not have provided adequate motivation to one having ordinary skill in the art to combine health testing and evaluation of treatments for individual patients as allegedly taught by Gatts with Menzie's alleged teaching that "the second outcomes data sets are collected from the plurality of individuals."

In addition, Appellants respectfully submit that Gatts and Menzie teach away from Lin. Gatts and Menzie relate to health testing and evaluation of treatments for an individual patient. In contrast, Lin discloses a system and method for producing quality control evaluation information for each instrument in a large group of instruments making up a peer group which periodically (such as daily) run a set of control samples from a common lot of control materials. See, e.g., Abstract. Specifically, Lin discloses that it will be clear to those skilled in the art, particularly in a medical application, that a laboratory will have many instruments performing different types of tests. The instruments can be rated with respect to peers, and thus a given laboratory may be a member of a number

of peer groups, typically one for each of its instruments. Thus, Lin is directed to instruments, control data from instruments, and distribution of concordance correlation coefficient's (CCC) for instruments. See, e.g., column 5, lines 58-67. Thus, Appellants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine health testing and evaluation of treatments for individual patients as taught by Gatts and Menzie based upon the collection of data for laboratory instruments as taught by Lin.

(iii) The Examiner now asserts that the combination of Gatts, Menzie, and Lin discloses the claimed invention. Appellants respectfully disagree. Appellants respectfully submit that Gatts relates to an individual patient's health testing and operational procedures of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. Thus, Gatts fails to disclose, or even suggest, collecting outcomes data sets "associated with one or more

medical procedures for a plurality of individuals," as recited in claim 1. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting multiple outcomes data sets for one or more indicators associated with one or more medical procedures for a plurality of individuals in multiple periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "a medical procedure," as recited in claim 1. In contrast, Gatts merely discloses modifying dynamic treatments of an individual patient in accordance with monitored data and to provide an optimized level of reconditioning therapy, and fails to disclose "a medical procedure."

Also, the Examiner acknowledges, and Appellants agree, that Gatts fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as recited in claim 1. The Examiner relies on column 2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed limitation. Appellants respectfully disagree. Specifically, Appellants respectfully

submit that even assuming *arguendo* that Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of claim 1. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. See, e.g., Menzie, column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's physiological data via collection devices 14a-14n and storing the physiological data at the processing center 20, but fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed.

In addition, Appellants respectfully submit that Gatts and Menzie, taken either alone or in combination, fail to disclose, or even suggest, a method for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers), as claimed. Indeed, Gatts and Menzie, taken either alone or in combination, fail to disclose, or even

suggest, a method for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) in any manner. In contrast, the present application claims a method for medical benchmarking using one or more user interfaces located at one or more user entities (e.g., surgical centers) wherein an outcomes monitoring report is generated comparing an outcomes result for a selected medical facility (e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., surgical centers). Thus, the present application is directed toward benchmarking a selected medical center (e.g., a surgical center) against multiple other medical facilities (e.g., surgical centers). The present application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, taken either alone or in combination, clearly fail to disclose, or even suggest, such claimed features.

IV. CONCLUSION

Appellants respectfully submit that the pending claims are allowable over the cited references. Accordingly, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the pending prior art rejections as set forth in the Final Office Action and reiterated in the Examiner's Answer. Also, Appellants respectfully submit that no other fees are required in connection with the filing of this Reply Brief. However, in the event that it is determined that a further fee is necessary to maintain the pendency of this application, the Commissioner is hereby authorized to charge Deposit Account No. 50-0206.

Respectfully submitted,

Hunton & Williams LLP

By


Thomas E. Anderson

Registration No. 37,063

TEA/DD

Hunton & Williams LLP
1900 K Street, N.W.
Washington, D.C. 20006-1109
Telephone: (202) 955-1500
Facsimile: (202) 778-2201

Date: September 28, 2009